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Attorneys for Defendant
NOVO NORDISK INC.

UNITED STATES DISTRICT COURT

SOUTHERN DISTRICT OF CALIFORNIA

IN RE INCRETIN-BASED THERAPIES PRODUCTS LIABILITY LITIGATION

This Document Relates to All Cases

Case No. 3:13-MD-02452-AJB-MDD

DECLARATION OF HEIDI LEVINE IN SUPPORT OF DEFENDANT NOVO NORDISK INC.'S MOTION TO STRIKE FROM THE PUBLIC DOCKET OR, IN THE ALTERNATIVE, TO SEAL PLAINTIFFS' EXPERT REPORTS REGARDING PREEMPTION

Judge: Hon. Anthony J. Battaglia

I, Heidi Levine, declare as follows:

1. I am an attorney with DLA Piper LLP (US), counsel for Defendant Novo Nordisk Inc. ("NNI"). I am licensed to practice in the State of New York. I have personal knowledge of the facts set forth herein. I submit this declaration in support of the Motion to Strike from the Public Docket or, in the Alternative, to Seal Plaintiffs' Expert Reports Regarding Preemption.

2. Several sections of Dr. Fleming's expert report (the "Fleming Report") discuss NNI's confidential and proprietary information and as demonstrated below, good cause exists to seal these confidential documents and the sections of the Fleming Report discussing the content of these documents.

3. The confidential sections of the Fleming Report that NNI seeks leave to maintain under seal are set forth below, in detail:

a. **Fleming Report, p. 40, para. 4, No. 2:** In this paragraph, Dr. Fleming incorporates confidential data from a draft internal slide presentation relating to clinical trials for NNI's obesity medication. This document was properly designated by NNI as confidential under the Protective Order in this case because it contains internal discussions regarding safety analysis and methodologies regarding the FDA Advisory Committee Meeting for NNI's obesity medication. This document also contains an internal stamp of "CONFIDENTIAL" and a legend restricting its use and disclosure. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

b. **Fleming Report, p. 41, para. 2, No. 4:** In this paragraph, Dr. Fleming incorporates proprietary data, internal analysis, and results of the same internal nonclinical study involving liraglutide and exenatide discussed below in Paragraph 3.c., and which was properly designated by NNI as confidential under the Protective Order in this case. This document also contains an internal stamp of "DRAFT" and "INTERNAL USE ONLY." Releasing this information to the

public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

c. **Fleming Report, p. 60, para. 1 relating to footnote 146 (Knudsen Deposition p. 134:6-137:11):** In this paragraph, Dr. Fleming incorporates methodologies and conclusions from the October 2, 2014 deposition testimony of Dr. Lotte Knudsen, which were properly designated by NNI as confidential under the Protective Order in this case and which relate to NNI's confidential and proprietary data, internal analysis, and results of an internal nonclinical study involving liraglutide and exenatide, a competitor product. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

d. **Fleming Report, p. 61, para. 3 relating to footnotes 148 and 149 (NOVO-02278271-96):** In this paragraph, Dr. Fleming incorporates information from a document properly designated as confidential under the Protective Order in this case, which relates to NNI's internal analysis of lipase study data. The information contained in this document reflects internal research results not released to NNI's competitors. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

e. **Fleming Report, p. 61, para. 3 relating to footnotes 148 and 150 (NOVO-02348487-539):** In this paragraph, Dr. Fleming incorporates proprietary data, internal analysis, and results of the same internal nonclinical study involving liraglutide and exenatide discussed above in Paragraph 3.a., and which was properly designated by NNI as confidential under the Protective Order in this case. This document also contains an internal stamp of "DRAFT" and "INTERNAL USE ONLY." Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

f. **Fleming Report, p. 61, para. 3 and footnote 151 (Knudsen Deposition p. 159:19-160:6):** In this paragraph, Dr. Fleming incorporates facts, conclusions, and a direct quotation from deposition testimony properly designated by NNI as confidential under the Protective Order in this case and which relate to NNI's proprietary data, analysis, and results of an internal nonclinical study involving liraglutide and exenatide discussed above in Paragraph 3.a. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

g. **Fleming Report, p. 65, para. 2 relating to footnote 158 (NOVO-00948679-9386):** In this paragraph and footnote, Dr. Fleming incorporates details from an August 23, 2013 Addendum to Clinical Overview, properly designated by NNI as confidential under the Protective Order in this case, and provides details concerning NNI's internal analysis of adverse event data from recent clinical studies. This document, also cited by Dr. Fleming in footnote 231, was properly designated by NNI as confidential under the Protective Order in this case because it discusses internal pharmacovigilance and safety analyses, contains an internal stamp of "CONFIDENTIAL" and a legend restricting its use and disclosure. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and analytical methods developed by NNI.

h. **Fleming Report, p. 65, para. 2 and footnote 159 (NOVO-00118902-77 and NOVO-00264339-5451):** In this paragraph and footnote, Dr. Fleming incorporates confidential details concerning NNI's internal analysis of adverse event data from recent clinical studies. One of the source documents, NNI's White Paper, which is the same document referenced by Dr. Fleming in footnotes 195, 202, and 203, was properly designated by NNI as confidential under the Protective Order in this case because it discusses internal pharmacovigilance and safety analyses, contains an internal stamp of "CONFIDENTIAL" and a legend

restricting its use and disclosure. The second document cited in this footnote, Development Safety Update Report ("DSUR") No. 1, also contains an internal stamp of "CONFIDENTIAL" and a legend restricting its use and disclosure. Further, like Periodic Safety Update Reports, DSURs are confidential. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

i. **Fleming Report, p. 65, para. 3 relating to footnote 160 (NOVO-01518117-80):** In this paragraph and footnote, Dr. Fleming incorporates confidential data from a draft internal slide presentation relating to clinical trials for NNI's obesity medication. This document was properly designated by NNI as confidential under the Protective Order in this case because it contains internal discussions regarding safety analysis and methodologies regarding the FDA Advisory Committee Meeting for NNI's obesity medication. This document also contains an internal stamp of "CONFIDENTIAL" and a legend restricting its use and disclosure. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

j. **Fleming Report, p. 78, para. 3 relating to footnote 195 (NOVO-00118902-77):** In this paragraph, Dr. Fleming incorporates confidential details concerning NNI's ongoing, proprietary clinical studies. This document, NNI's White Paper, which is the same document referenced by Dr. Fleming in footnotes 159, 202, and 203, was properly designated by NNI as confidential under the Protective Order in this case. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

k. **Fleming Report, p. 79, para. 3 and p. 80, para. 1 relating to footnote 200 (NOVO-01022167-541):** In these paragraphs and footnote, Dr. Fleming describes confidential details of an ongoing, proprietary study of

liraglutide. This document, properly designated by NNI as confidential under the Protective Order in this case, also contains an internal stamp of "CONFIDENTIAL" and a legend restricting its use and disclosure. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

l. **Fleming Report, p. 80, para. 2 relating to footnotes 202 and 203 (NOVO-00118902-77 and NOVO-02153958-4002):** In this paragraph and footnotes, Dr. Fleming describes confidential details of an ongoing, proprietary study of liraglutide. One of the source documents, NNI's White Paper, which is the same document cited by Dr. Fleming in footnotes 159 and 195 was properly designated by NNI as confidential under the Protective Order in this case, contains an internal stamp of "CONFIDENTIAL" and also contains a legend restricting its use and disclosure. The other source document, a proprietary interim study report, has a "RESTRICTED" designation and was marked confidential under the Protective Order in this case. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

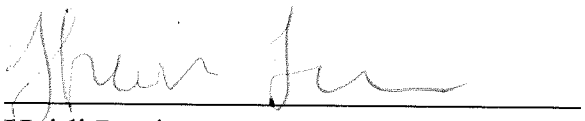
m. **Fleming Report, p. 82, para. 2 relating to footnote 207 (NOVO-00949394-5):** In this paragraph, Dr. Fleming includes details about confidential regulatory correspondence with the EMA concerning liraglutide. NNI properly designated this document as confidential under the Protective Order in this case. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and methods developed by NNI.

n. **Fleming Report, p. 94, para. 1 relating to footnote 231 (NOVO-00948679-9386):** In this paragraph, Dr. Fleming incorporates data from an August 23, 2013 Addendum to Clinical Overview, providing details about its content which describe NNI's internal analysis of adverse event data from recent

clinical studies, and properly designated by NNI as confidential under the Protective Order in this case. This document also cited by Dr. Fleming in footnote 158, contains an internal stamp of "CONFIDENTIAL" and a legend restricting its use and disclosure. Releasing this information to the public or co-Defendants would allow competitors to benefit from the proprietary research and analytical methods developed by NNI.

I declare under penalty of perjury under the laws of the United States that the foregoing is true and correct.

Executed on January 6, 2015 in the State of New York.



Heidi Levine